

Exhibit 24

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 30, 2002

Organogenesis Inc.
(Exact name of registrant as specified in its charter)

Delaware	1-09898	04-2871690
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(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

150 Dan Road
Canton, MA 02021

(Address of principal executive offices) (Zip Code)

Registrant's telephone number, including area code: (781) 575-0775

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Item 5. Other Events.

On January 30, 2002, the Registrant filed a Registration Statement on Form S-3 to register the resale of shares held by certain of its selling securityholders. As a part of that document, the Registrant included an updated set of risk factors relating to its business. The Registrant intends, by filing such updated risk factors with this Current Report on Form 8-K, to provide such risk factors as part of its documents filed pursuant to the Securities Exchange Act of 1934.

The following are the risk factors which were included in the Form S-3 filed with the Commission on January 30, 2002.

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below before making an investment decision. You should also refer to the other information included in or incorporated by reference into the Company's public filings with the Commission, including our consolidated financial statements and related notes. The risks and uncertainties described below are those that we currently believe may materially affect our company. Additional risks and uncertainties that we are unaware of or that we currently deem immaterial also may become important factors that affect our company. If any of the following risks actually occurs, our business, operating results or financial condition could be materially adversely affected, the trading price of our common stock could decline and you could lose all or part of your investment.

We have a history of losses, we expect to continue to incur losses and our future profitability is uncertain.

We have incurred significant operating losses in funding the research, development, testing and marketing of our products in every year of our existence. We incurred net losses of \$14,031,000 for the year ended December 31, 1998, \$28,350,000 for the year ended December 31, 1999, \$28,605,000 for the year ended December 31, 2000 and \$22,561,000 for the nine months ended September 30, 2001. The extent of future losses and the time required to achieve profitability are highly uncertain, and we may never achieve a profitable level of operations or, even if we achieve profitability, we may not be able to sustain it on an ongoing basis.

We will need to raise additional funds by the end of the first quarter of 2002, but may be unable to raise the funds, in which case we would have to curtail or discontinue our activities.

We will seek to raise \$15 million from the sale of equity securities that have not been registered under the Securities Act of 1933; such securities may not be sold in the United States absent registration or an exemption from registration. Based upon our current forecasts, we believe that proceeds from proposed equity financings of approximately \$15 million, together with our existing cash, cash equivalents and credit line and product and other revenues, will be sufficient to finance operations through at least the next twelve months. This projection is based on assumptions regarding our operating cash requirements and revenues from sales of Apligraf and other products, any of which could prove to be incorrect. We are currently seeking additional funding but our research, development, manufacturing and other activities may require that we raise substantial additional funds. We may not be able to obtain the proposed \$15 million in new financing or any additional funding on terms favorable to us or our stockholders, if at all. Equity financings would dilute your ownership in us.

Factors that may increase our cash requirements above our forecasts or require us to raise more funds than anticipated include:

- failure to achieve sales volume forecasts;
- delays in obtaining regulatory approvals of products in different countries, if needed, and subsequent timing of product launches;
- delays in commercial acceptance and reimbursement when product launches occur;
- changes in the progress of research and development programs or initiation of new programs;
- changes in the resources devoted to outside research collaborations or projects, self-funded projects, proprietary manufacturing methods and advanced technologies; and
- acceleration of the convertible subordinated promissory note that we issued to Novartis in October 2001, which could occur if we default on our obligations under the note.

Although we have a contractual put option to sell an additional \$10 million of our securities to Novartis, we must satisfy a number of conditions in order to exercise that option. If we do not satisfy these conditions and Novartis is unwilling to waive any unsatisfied conditions, we will be unable to sell additional securities to Novartis pursuant to the put option. In addition, even if we satisfied the conditions, the closing would occur no sooner than 90 days following the day we send the put option exercise notice. If adequate funds are not available to us when needed, we will be required to delay, scale back or eliminate our research and development programs or license to third parties products or technologies that we would otherwise undertake to develop ourselves and otherwise reduce our level of operations. The failure to have adequate liquidity could result in our receiving a "going concern" opinion from our auditors.

We have entered into collaboration agreements with Novartis and other parties to market our products and we may enter into additional collaboration agreements in the future. If these parties do not perform their obligations or terminate these agreements, it will impair our ability to commercialize our products.

We have limited experience in sales, marketing and distribution. For this reason, we have developed long-term strategic relationships with parties that have marketing and sales forces with technical expertise and distribution capability necessary to commercialize our products. We entered into a license and supply agreement with Novartis pursuant to which we granted to Novartis exclusive, worldwide marketing rights for our lead product, Apligraf. We have also entered into collaboration agreements with Biomet, Inc. for the development and marketing of orthopedic and periodontal applications of our FortaFlex technology and with Royce Medical Company for the sale of our PuraPly product in non-hospital settings.

Our revenues will depend substantially upon the efforts of Novartis, which may or may not be successful in marketing and selling Apligraf. We cannot control the amount and timing of resources that Novartis may devote to marketing and selling Apligraf or its ability or willingness to continue its investment in such activities. Our license and supply agreement with Novartis will terminate when Novartis no longer has any payment obligations to us under the agreement. The payment obligations under the agreement terminate with respect to a particular country upon the later of (1) the expiration of the patent rights related to Apligraf in that country, or (2) 10 years after the first commercial sale in that country following governmental marketing approval or clearance in that country. Payment obligations with respect to sales of Apligraf in the United States would thus terminate no earlier than 2013. The license and supply agreement may be terminated sooner for various reasons, including:

- if either party commits a material breach of the terms of the agreement;
- if either party becomes insolvent or files for bankruptcy;
- if Novartis discontinues the development of Apligraf including for reasons of safety or efficacy; or

if a competitor of Novartis acquires substantially all of our assets or 40% or more of our voting stock.

For any number of reasons, we may not be able to maintain a successful long-term strategic relationship with Novartis. If Novartis does not perform its obligations as expected or if Novartis has a strategic shift in its business focus, it would be difficult for us to continue to expand sales of or successfully commercialize Apligraf. Our failure to achieve broad use of Apligraf in the market would hurt our ability to generate revenues and any future profits.

To the extent that we are unable to maintain our relationship with Novartis, we may need to reach agreement with another partner or may require more capital and resources to undertake a commercialization program for Apligraf at our own expense. In addition, we could encounter significant delays in introducing Apligraf into target markets or find that the commercialization of Apligraf in those markets is adversely affected by the absence of a strategic relationship with a pharmaceutical company.

In addition, we are currently discussing an amendment to the license and supply agreement and related agreements with Novartis that could, if we reach an agreement, provide for, among other things, an option to purchase our Apligraf-related assets in the event we are in a voluntary or involuntary bankruptcy proceeding, or in a similar financial condition. Although we agreed to use our good faith, best efforts to negotiate with Novartis, we are under no obligation, however, to reach any agreement with Novartis for an amendment to the license and supply agreement and related agreements.

We produce Apligraf at a single location and, if we were unable to utilize this facility, we would not be able to manufacture and sell Apligraf for approximately two years.

We produce Apligraf at a single manufacturing facility located in Canton, Massachusetts. Damage to our manufacturing facility due to fire, contamination, natural disaster, power loss, unauthorized entry or other events could cause us to cease the manufacturing of Apligraf. If our manufacturing facility were destroyed, it would take approximately two years to rebuild and qualify another viable manufacturing facility, and we would not be able to sell Apligraf during the intervening period. In addition, if our manufacturing facility fails to comply with FDA and other regulatory requirements, we will be required to suspend the manufacturing of Apligraf.

If we cannot increase our manufacturing capacity for larger-scale production, we will not be able to earn substantial revenues from the sale of Apligraf.

We have been producing Apligraf for commercial sale since the second half of 1997. However, as the demand for Apligraf increases, we must further transition from small-scale to full-scale production of our products. If we do not make the full-scale transition successfully, we will not be able to satisfy the demand for our products and our results of operations will be hurt.

Because the manufacturing process for Apligraf is complicated and time-consuming, we may experience problems that would limit our ability to manufacture and sell Apligraf which would negatively impact our results of operations.

As with any manufactured product, problems can occur during our production processes for Apligraf. These problems can result in increased product scrap, which can reduce our operating margins. These problems could also require us to delay Apligraf shipments, recall previously shipped product or be unable to supply Apligraf for a period of time, all of which could negatively impact our results of operations. We have on occasion instituted product recalls, which were not material. Contamination or defects could result in a material recall in the future, which could adversely affect our results of operations.

Our markets are competitive and our competitors could develop more effective products.

We are engaged in the rapidly evolving and competitive field of tissue engineering for the treatment of skin wounds and other medical needs. Our competitors include tissue engineering companies, xenotransplant companies, wound care divisions of major pharmaceutical companies and other

pharmaceutical, biotechnology and medical products companies using traditional technologies to develop products for wound care. Three of our competitors are Ortec International, Inc., Advanced Tissue Sciences, Inc. and J&J DePuy, an affiliate of Johnson & Johnson, Inc. Some of our competitors have much greater resources, research and development staffs and facilities, experience in conducting clinical trials and obtaining regulatory approvals and experience in the manufacturing, marketing and distribution of products than we do. Our competitive position is based upon our ability to:

- create and maintain scientifically-advanced technology and proprietary products and processes;
- attract and retain qualified personnel;
- obtain patent or other protection for our products and processes;
- obtain required government approvals on a timely basis;
- manufacture products on a cost-effective basis; and
- successfully market products.

If we are not successful in meeting these goals, our business could be hurt. Our competitors may succeed in developing technologies, products or procedures that are more effective than any that we are developing or that would render our technology and products obsolete, noncompetitive or uneconomical. One of our competitors, Advanced Tissue Sciences, received FDA approval in October 2001 for a tissue-engineered, living dermal substitute for the treatment of chronic diabetic foot ulcers. This product directly competes with Apligraf.

We may not successfully develop and market our products and products under development and, if we do not, we will not achieve profitability.

Our products are subject to the risks of failure inherent in the development of innovative health care technologies and the marketing of medical products based on these technologies. These risks include the possibility that:

- our products will be found to be unsafe, ineffective or cause adverse reactions or will otherwise fail to meet or maintain applicable regulatory standards or receive necessary regulatory clearances;
- third parties will market superior or equivalent products or that our products will not gain broad acceptance by the medical community;
- our products will be difficult or uneconomical to manufacture and market on a large scale;
- our products will fail to achieve or be delayed in achieving acceptable insurance or other third-party reimbursement; or
- proprietary rights of third parties will preclude us from marketing our products.

Our business results will be hurt if we are unable to demonstrate to the medical community the efficacy, relative safety and cost-effectiveness of treating patients with our products or if our products are not accepted as alternatives to other existing or new therapies. Any future negative events or unfavorable publicity involving the use of our products could also adversely affect the acceptance of our products.

Our ability to develop, manufacture and market our products depends upon our compliance with government regulations and obtaining governmental approvals to market our products.

Our present and proposed products are subject to extensive and rigorous regulation by governmental authorities in the United States and other countries. To clinically test, produce and market medical products for human use, we must satisfy requirements established by the FDA and comparable foreign regulatory agencies. Typically, those rules require that products be approved by the government agency as safe and effective for their intended use prior to being marketed. The approval process is expensive, time consuming and subject to unanticipated delays. Our product candidates may not be approved. For example, although Apligraf is regulated as a medical device in the United States, the European Union regulates Apligraf as a drug, which may subject the product to a more extensive regulatory approval process than that in effect for medical devices. Novartis filed an application for regulatory approval for Apligraf with the European Medical Evaluation Agency, or EMEA, in April 2001. With our concurrence, Novartis withdrew that application for regulatory approval for Apligraf in November 2001 to give us time to complete the portion of our manufacturing facility that would be used to produce Apligraf for sale in Europe and to meet other European regulatory requirements. Novartis has agreed with us to use commercially reasonable efforts to resubmit its application for regulatory approval as soon as reasonably practical, but we cannot be certain when this will occur, if at all. There can be no assurance that we will obtain EMEA approval for Apligraf on a timely basis, if at all. The FDA and comparable foreign regulatory agencies may withdraw our product approvals for failure to comply with regulatory standards for unforeseen problems with the products.

We must test our products to determine their safety and efficacy before a submission may be filed with the FDA to obtain authorization to market regulated products. In addition, the FDA imposes various requirements on manufacturers and sellers of products under its jurisdiction, such as adherence to labeling, good manufacturing practices, record keeping and reporting requirements. Numerous regulations also govern the storage and marketing of our products. The FDA and foreign regulatory authorities have limited experience with our technology and products. As a result, our products are susceptible to requests for clinical modifications or additional supportive data, or changes in regulatory policy, which could substantially extend the test period for our products resulting in delays or rejections. Even after substantial time and expense, we may not be able to obtain regulatory product approval by the FDA or foreign authorities for a product or clinical indication. The FDA also may require post-marketing testing and surveillance programs for an approved product. Furthermore, changes in existing regulations or the adoption of new regulations could prevent us from obtaining, or affect the timing of, future regulatory approvals or could negatively affect the marketing of our existing products. We would not be able to commercialize our products as planned and our operating results would be hurt if:

- . the regulatory agencies find our testing protocols to be inadequate;
- . the appropriate authorizations are not granted on a timely basis, or at all;
- . the process to obtain authorization takes longer than expected or we have insufficient funds to pursue those approvals;
- . we lose previously-received authorizations; or
- . we do not comply with regulatory requirements.

We are the sole-source manufacturer of Apligraf and have contracted with a third party to manufacture our PortaFlex line of products. We are required to maintain our manufacturing facility in compliance

with the FDA's good manufacturing practices/quality systems regulations. Manufacturing facilities are usually subject to an FDA inspection before a new product is approved and are subject to continual review and periodic inspection. The discovery of previously unknown problems with our or our contract manufacturers' manufacturing processes could result in restrictions on the applicable product or withdrawal of the product from the market. Foreign regulatory agencies can also impose manufacturing controls and inspections. We may not be able to maintain the necessary regulatory approvals for our manufacturing operations or manufacture our products in a cost-effective manner. If we are unable to manufacture potential products independently or obtain or retain third party manufacturing on commercially acceptable terms, our submission of products for final regulatory approval and initiation of marketing would be delayed. This, in turn, may prevent us from commercializing product candidates as planned, on a timely basis or on a profitable basis.

Medical and biopharmaceutical research and development involves the controlled use of hazardous materials, such as radioactive compounds and chemical solvents. We are subject to federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of those materials and waste products. In addition, we handle and dispose of human tissue. Although we believe that our safety procedures for handling these materials are adequate, we could be liable for damages if accidental contamination or injury were to occur. We do not maintain insurance for damages arising from accidental contamination or injury.

We have limited independent marketing experience and therefore may be unable to commercialize products for which we have not established collaborative relationships. If we are not successful in marketing these products, we will not realize any revenue from sales of these products.

We commenced the commercialization of FortaPerm in October 2001. We expect to commence the commercialization of PuraPly and FortaGen in the first quarter of 2002. Prior to commencement of marketing and sales activities for our FortaFlex line of products, we had no experience in commercializing our products independently. Due to our inexperience in commercializing our own products, we may not be successful in selling these or other products directly to doctors and hospitals without the assistance of a strategic partner. These commercialization efforts will require investments for marketing and sales infrastructure and will require us to incur additional operating expenses on an ongoing basis. If we are not successful in these commercializing efforts, we will not realize product revenues and our financial condition will be harmed.

We rely heavily upon patents and proprietary technology that we own and that we license from others. If third parties violate our intellectual property rights or those intellectual property rights that we license from others, we may not be able to compete in the market.

We rely upon our portfolio of patents, patent applications and licenses to patents and patent applications relating to living tissue products, organ assist treatments and other aspects of tissue engineering. We currently have rights in 18 patents issued in the United States, 10 patents issued in Europe and 7 patents issued in Japan. As part of our continuing interest in protecting our intellectual property rights, we have filed and are prosecuting 17 other patent applications in the United States. We license some of our technologies under an exclusive patent license agreement with the Massachusetts Institute of Technology. The agreement with MIT covers U.S. patents and corresponding patents in Europe and Japan. We license one of the key U.S. patents directed to our lead product Apligraf under the MIT agreement. This patent expires in 2006 and the other key U.S. patent underlying the Apligraf technology, which we own, expires

in 2013. Pursuant to the MIT agreement, MIT granted us an exclusive, worldwide license to make, use and sell the products covered by its patents and to practice the procedures covered by its patents. Additionally, we have purchased intellectual property related to our liver assist device program from Baxter Healthcare Corporation. This intellectual property includes two issued U.S. patents and one pending U.S. patent, as well as corresponding international patents.

We aggressively patent and protect our proprietary technologies. However, additional patents may not be issued to us from our domestic or foreign patent applications. Third parties may challenge, invalidate or design around our patents. Third parties may infringe or independently develop either the same or similar technology as that covered by our patents or those patents licensed to us. Similarly, our patents may not provide us with meaningful protection from competitors and, as a result, our competitors could compete more directly with us.

In addition to our patent portfolio, we rely upon unpatented proprietary technology, know-how and trade secrets and seek to protect them through confidentiality agreements with employees, consultants and advisors. We request that any corporate sponsor with which we enter into a collaborative agreement do so as well. If these confidentiality agreements are breached, we may not have adequate remedies for the breach. In addition, third parties may independently develop or otherwise acquire substantially the same proprietary technology as our technology and trade secrets.

We have relationships with a number of academic consultants who are not employed by us. Accordingly, we have limited control over their activities and can expect only limited amounts of their time to be dedicated to our activities. These persons may have consulting, employment or advisory arrangements with other entities that may conflict with or compete with their obligations to us. Our consultants typically sign agreements that provide for confidentiality of our proprietary information and results of studies. However, in connection with every relationship, we may not be able to maintain the confidentiality of our technology. The dissemination of our technology could hurt our competitive position and results of operations. To the extent that our scientific consultants independently develop inventions or processes that may be applicable to our proposed products, disputes may arise as to the ownership of the proprietary rights to that information. We may not prevail in these disputes.

Our ability to compete effectively will depend, in part, on our ability to maintain the proprietary nature of our technology and manufacturing processes. If we are unsuccessful in protecting our intellectual property rights, sales of our products would suffer and our ability to generate revenues could be severely impacted.

Claims by third parties that our patents are invalid or that our products or production methods infringe their rights could prevent us from selling our products or subject us to substantial costs and liabilities.

Third parties may claim that our products or production methods infringe upon their intellectual property rights. This risk is exacerbated by the fact that the validity and breadth of medical technology patents involve complex legal and factual questions for which important legal principles remain unresolved. While we are not currently aware of any pending or threatened claim of infringement, our competitors or other third parties may assert in the future that our products or the methods we employ are covered by their patents. For example, we are aware of issued patents in the markets we currently serve and propose to serve that are held by third parties. We do not license or have other rights to these patents. We believe

that the manufacture, use or sale of Apligraf does not and would not infringe any valid patents of these third parties and that other defenses would be available to us if a third party brought a claim relating to these patents against us. As we do not license or have other rights to these patents, if we were forced to defend infringement litigation, a court might disagree with our view and we might not be able to establish invalidity or non-infringement. In particular, establishing invalidity requires clear and convincing evidence sufficient to overcome the presumption of validity that issued patents enjoy by law.

In addition, because patent applications can take many years to issue, there may be currently pending applications of which we are unaware, that may later result in issued patents which our products may infringe. There could also be existing patents of which we are not aware that our products may infringe.

If an infringement lawsuit were to be asserted against us and we lost, a court could require us to pay substantial monetary damages. Moreover, a court could prevent us from selling the infringing product unless we obtained a license to use the technology covered by the patents or redesigned our product to avoid infringement. A license may not be available at all or on terms acceptable to us, or we may not be able to redesign a product to avoid infringement. Modification of a product or development of a new product could require us to conduct additional clinical trials and to revise our filings with health regulatory agencies, which could be time-consuming and expensive. We would be materially harmed if we were unable to successfully defend infringement litigation, were unable to obtain any required license or sublicense to a patent that we were held to infringe or were unable to design around the asserted patent.

If we are unable to obtain adequate sources of supply of the raw materials, components and specialized equipment needed to manufacture Apligraf, our ability to continue generating revenue from sales of Apligraf will be impaired.

We obtain the raw materials, components and specialized equipment used to manufacture Apligraf from numerous suppliers. Three components are currently obtained from sole-source suppliers. We maintain an inventory of the necessary raw materials, components and specialized equipment that we believe is sufficient to avoid a disruption in the production of Apligraf in the event of the temporary unavailability of these raw materials, components and specialized equipment. Because the FDA approval process requires manufacturers to specify their proposed materials of some components in their applications, FDA approval of a new material would be required if a currently approved material became unavailable from a supplier. If one or more of our suppliers ceased production of the necessary raw materials, components and specialized equipment of Apligraf, however, we would need time to qualify replacement suppliers and the manufacture of Apligraf could be disrupted.

The components used to manufacture Apligraf that we obtain from sole-source suppliers are (1) insulin, a growth hormone, (2) media, a liquid used to provide nutrients to Apligraf as the cells grow, and (3) transferrin, a plasma protein. If our supply of any one of these components were interrupted, we would be unable to manufacture Apligraf. We believe that it could take up to one year to qualify another supplier. We are currently attempting to qualify alternative suppliers. To date, we have not experienced difficulty in obtaining any of the components necessary to manufacture Apligraf. We believe that a number of alternate suppliers could provide the raw materials and components used to manufacture Apligraf.

The thermo-formed tray assembly that we use in the manufacturing process of Apligraf is a specialized piece of equipment that is available to us under a supply arrangement with only one manufacturing

source. If we are unable to obtain adequate supplies of thermo-formed tray assemblies to meet future Apligraf manufacturing needs or if we cannot obtain those assemblies on a cost-effective basis, our operations would be hurt.

We also use collagen, a protein obtained from animal source tissue, as another significant material required to produce our products. We have developed a proprietary method of procuring our own collagen that we believe is superior in quality and strength to collagen available from commercial sources. We may not be able to obtain adequate supplies of animal source tissue, or to obtain this tissue from animal herds that we believe do not involve pathogen contamination risks, to meet our future needs or on a cost-effective basis.

Interruptions in our supply of raw materials, components and specialized equipment may occur in the future or we may have to obtain alternative vendors for these items. Any significant supply interruption could adversely affect the production of Apligraf or other products and delay our product development or clinical trial programs. These delays would have an adverse effect on our revenues.

We depend on our key personnel to manage our business and maintain our competitive position.

We are highly dependent upon the principal members of our management team, especially our chief executive officer, Michael L. Sabolinski, M.D. We are currently negotiating an employment agreement with Dr. Sabolinski. We do not have employment agreements with other key personnel. Furthermore, we do not maintain key-man life insurance for our key personnel. The loss of the services of any of our key personnel could adversely affect our ability to develop and market our products, to obtain necessary regulatory approvals, to achieve our business objectives, to raise additional funds and to attract strategic and collaborative partners. We have commenced a search for a Chairman of the Board.

Because of the specialized nature of our business, our success will depend upon our ability to attract and retain highly qualified personnel. The competition for experienced personnel among biotechnology, pharmaceutical and healthcare companies, universities and non-profit research institutions is intense. If we are unable to continue to attract and retain highly qualified personnel, our competitive position could be hurt.

We may incur material losses and costs as a result of product liability claims that may be brought against us and our insurance may not be sufficient to cover damages.

Our business exposes us to potential liability risks that are inherent in the testing, manufacturing, marketing and sale of medical products. The use of our products and product candidates, whether for clinical trials or commercial sale, may expose us to product liability claims or product recall and possible adverse publicity. These claims could be based on, among other things, the presence of any impurity or pathogen in any of our products. Our products are derived from human and animal products, must be handled numerous times during the production process and, in the case of our living cell products, cannot be manufactured subject to final sterilization, all of which increase the risk that an impurity or pathogen could be present. Although we have product liability insurance coverage, the level or breadth of our coverage may not be adequate to fully cover potential liability claims. In addition, we may not be able to obtain additional product liability coverage in the future at an acceptable cost. A successful claim or series of claims brought against us in excess of our insurance coverage and the effect of product liability litigation upon the reputation and marketability of our technology and products, could harm our business.

Our business is subject to the uncertainty of third-party reimbursement and health care reform measures which may limit market acceptance.

In both domestic and foreign markets, our ability to commercialize our products and product candidates depends, in part, upon the availability of reimbursement from third-party payors, such as government health administration authorities, private health insurers and other organizations. Third-party payors increasingly challenge the price and cost-effectiveness of medical products. If our products are not considered cost-effective, third-party payors may limit reimbursement. Government and other third-party payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA and by refusing, in some cases, to provide any coverage for uses of approved products for disease indications for which the FDA has not granted marketing approval. Use of Apligraf for indications other than those approved by the FDA remain subject to uncertainties regarding third-party reimbursement. If government and third party payors do not provide adequate coverage and reimbursement levels for uses of Apligraf or any of our other products, the market acceptance of those products would be limited.

There have been a number of federal and state proposals during the last few years to subject the pricing of pharmaceuticals to government control and to make other changes to the U.S. health care system. It is uncertain what legislative proposals will be adopted or what actions federal, state or private payors for health care goods and services may take in response to any health care reform proposals or legislation. We cannot predict the effect that health care reforms may have on our business.

We may face interruptions in the production and shipping of our products due to delays or stoppages in transportation, mail or related services.

Because our products contain living tissue and can only be stored for limited periods of time, our customers typically purchase our products on an as-needed basis and we must ship our products using overnight carriers. Delays or stoppages in transportation, mail or other related services within the United States and throughout the world may prevent us from shipping our products to our customers resulting in lost sales. The inability to ship our products also results in the loss of inventory as the production of a batch of Apligraf cannot be stopped and restarted. The inability to ship our products and the resulting expense of lost inventory could have a material adverse effect on our business, results of operations and financial condition.

Our stock price has been volatile, and can fluctuate significantly based on events that are not in our control and general industry conditions. This volatility may make it more difficult to realize a gain on an investment in our stock.

The biotechnology sector is vulnerable to abrupt changes in investor sentiment. Stock prices of companies in the biotechnology industry, including us, can swing dramatically, with little relationship to operating performance. Our stock price may be affected by a number of factors including, but not limited to:

- . clinical trial results, regulatory decisions and other product development events;
- . the outcome of litigation;
- . decisions relating to intellectual property rights;
- . the entrance of competitive products into our market;
- . changes in reimbursement policies or other practices related to the pharmaceutical industry;

- . other industry and market changes or trends;
- . the timing of approval and commercialization of our products;
- . the results of research or scientific discoveries by us or others;
- . new technological innovations;
- . developments concerning technology rights; or
- . public perception regarding the safety and efficacy of our products.

During the period from January 29, 1999 to January 29, 2002, the price of our common stock, adjusted for stock splits, has ranged from \$2.35 to \$19.50 per share. These fluctuations can occur due to events outside of our control, regulatory actions such as government approval of products or reimbursements and general market conditions affecting the biotechnology sector or the stock market generally. Fluctuations in our financial performance from period to period, the issuance of analysts' reports and general industry and market conditions also may have a significant impact on the market price of our common stock.

If we cannot meet the American Stock Exchange maintenance rules and requirements for continued listing, the American Stock Exchange may delist our common stock, which would negatively impact the price of our common stock and your ability to sell our common stock.

Our common stock is listed on the American Stock Exchange, or AMEX. The AMEX rules provide that the AMEX may consider delisting when a company has, among other things, (a) sustained losses in two of its three most recent fiscal years and has stockholders' equity of less than \$2 million or (b) sustained losses from continuing operations and/or net losses in each of its five most recent fiscal years. We currently do not satisfy these criteria. In December 2001, the AMEX agreed to continue our listing pending a review of our progress in meeting these criteria as reflected in our Form 10-K for 2001. We agreed to raise additional funds in the first quarter of 2002 and to report to the AMEX by April 15, 2002 regarding our progress in raising capital and meeting projected operating results. We believe that the proceeds of our proposed sale of \$15 million of equity securities, together with the conversion of our 7% convertible promissory notes issued in 1999 and our 7% convertible promissory note issued to Novartis in 2001, would allow us to meet the stockholders' equity criterion. The consent of the holders of these notes is required to effect conversion of these notes, and the consent of the holders of the 1999 notes may require the conversion price applicable to those notes (currently \$14.50) to be modified, which modification would require Novartis' consent. If we are unable to obtain such consents, we will need to raise more than \$15 million in additional capital to meet the stockholders' equity criterion.

We cannot provide any assurance that our common stock will remain listed on the AMEX or that we will not be delisted if we fail to meet these listing criteria. In the event our common stock is delisted from the AMEX, you would find it more difficult to trade in our common stock and may find it more difficult to obtain accurate, current information concerning market prices for our common stock. In addition, we would find it more difficult to raise equity financing if our common stock is delisted.

If we default on our obligations under the convertible subordinated promissory note that we issued to Novartis, we may be required to repay to Novartis the full principal amount of the note, together with interest, and we may incur additional financial obligations to Novartis.

Under the terms of the convertible subordinated promissory note that we issued to Novartis as of September 28, 2001, Novartis may declare the full principal amount of the note, together with all accrued but unpaid interest on the note and other amounts that we owe to Novartis on the date of acceleration, to be immediately due and payable in cash upon the occurrence of an event of default. As of January 30, 2002, there was \$10 million in principal amount outstanding under the note, which is due on March 29, 2004. Interest on the note accrues at 7% annually and is payable on September 30 and March 31 of each

year. Although we are entitled to deliver shares of our common stock in satisfaction of the note at any time after March 31, 2002, we must satisfy a number of conditions, some of which cannot be satisfied without a waiver from Novartis. Any one of the following events will constitute an event of default under the note:

- our default in the timely payment to Novartis of the principal amount of, interest on or liquidated damages in respect of the note;
- any representation or warranty that we made to Novartis proves to have been incorrect when we made it under the note or the agreement under which the note was issued;
- our failure to observe or perform any covenant or agreement under, or our breach of, the note or the agreement pursuant to which the note was issued which is not remedied by us within 30 days of notice thereof;
- any bankruptcy, insolvency or reorganization proceedings involving us or any of our subsidiaries; or
- the delisting or suspension of our common stock from trading on the AMEX without being relisted for a period of 30 trading days.

If we default on our obligations under the terms of the note and are required to repay to Novartis all or a large portion of the amounts owed under the note, our financial condition and results of operations would be significantly adversely affected.

Our anti-takeover provisions may deter potential acquirors and may depress our stock price.

We, as a Delaware corporation, are subject to the General Corporation Law of the State of Delaware, including Section 203, an anti-takeover law enacted in 1988. In general, Section 203 restricts the ability of a public Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder. As a result of the application of Section 203 and provisions in our restated certificate of incorporation, as amended, and by-laws, potential acquirors may be discouraged from attempting to acquire us, thereby possibly depriving our stockholders of acquisition opportunities to sell or otherwise dispose of our stock at above market prices typical of these acquisitions.

We have also adopted a shareholder rights plan, which gives holders of our common stock the right to purchase shares of our Series B Junior Participating Preferred Stock if a potential acquiror purchases 15% or more of our outstanding common stock or plans to make a tender offer to purchase 30% or more of our outstanding common stock. The existence of this plan may make it more difficult for a third party to acquire control of us.

We are authorized to issue up to 1,000,000 shares of preferred stock, \$1.00 par value per share, and to determine the price, privileges and other terms of these shares. The issuance of any preferred stock with superior rights to our common stock could reduce the value of our common stock. In particular, specific rights granted to future holders of preferred stock could be used to restrict our ability to merge with or sell our assets to a third party, thereby preserving control of us by present owners and management and preventing the holders of our common stock from realizing a premium on their shares.

The value of your securities may decrease if other security holders exercise their options and warrants or if their debt is converted.

At December 31, 2001, 37,074,900 shares of our common stock were outstanding, which excludes 250,000 treasury shares. We have reserved an additional 11,164,467 shares of our common stock for issuance under our employee stock purchase plan and upon the exercise of outstanding stock options and warrants, the exercise of stock options available for grant under our option plans and the conversion of issued convertible notes. We plan to grant additional options in the future. If any of these securities are exercised or converted, investors may experience dilution in the market value and earnings per share of the common stock into which these securities are convertible.

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SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Organogenesis Inc.
(Registrant)

Date: January 30, 2002

/s/ John J. Arcari

John J. Arcari
Chief Financial Officer

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